

REMARKS

The amendment canceling the claims was necessary because when the file was transferred to the present attorneys, it did not contain any preliminary amendment, canceling claims 1-58 and adding claims 59-110. The present attorneys first knowledge of these claims came after a notice from the Patent Office dated 10/08/03, advising of a non-compliant response. The undersigned attorney performed an on-line search of the status of the application and discovered the preliminary amendment. The undersigned attorney determined that the assignee did not have a copy of the amendment in their files. The undersigned attorney left a voice mail message with Examiner Snow on 02/06/03, requesting a facsimile copy of the amendment. However, the Examiner never returned the telephone call or faxed a copy of the claims. Accordingly, the Applicants submit this amendment, adding claims 111-128 which are directed to Species 3-- the embodiment of Fig. 7.

Support for claims 111-128 is found throughout the specification. In particular, claims 111 and 126, which are directed to an assembled bone implant, comprising two portions of cortical bone, having a through hole in the cortical bone and being held together with a bone pin is found throughout the specification, including at page 5, lines 11-16; page 16, lines 13-30; Figs. 7A - 7B, page 17, lines 10-22; and Figs. 8A - 8B.

Claim 112, which is directed to the assembled bone implant of claim 111, wherein said first cortical bone portion and said second cortical bone portion each have a "D shape," is supported throughout the specification, including Fig. 7, showing the elected implant of Fig. 7 having the shape of the capital letter "D."

Claim 113, which is directed to the assembled bone implant of claim 112, wherein said first cortical bone portion is "stacked" over said second cortical bone portion, is supported throughout the specification, including at page 16, lines 13-15 ("In Figure 7, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as to allow **stacking** thereof"); emphasis added in bold.

Claim 114, which is directed to the “assembled bone implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium,” is supported throughout the specification, including at page 5, lines 15-16 (“appropriate retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium and other metallic retention pins”).

Claim 115, which is directed to the assembled bone implant of claim 114, ‘wherein said retention pin is cortical bone,’ is supported throughout the specification, including at page 5, line 15 (“appropriate **retention pins** made from any desirable material, including **cortical bone**. . .”); and at page 16, line 23 (“**Pins**, composed of **cortical bone**. . .”); emphasis added in bold.

Claim 116, which is directed to the assembled bone implant of claim 111, wherein said first cortical bone portion is a “mirror image” of said second cortical bone portion, is supported throughout the specification, including at page 3, lines 8-9 (“Figure 8 provides several views of an implant of this invention formed by juxtaposition of **mirror half images** of the implant. . .”); emphasis added in bold.

Claim 117 which is directed to the assembled bone implant of claim 112, wherein the graft has “a beveled edge of defined radius,” is supported throughout the specification, including at page 9, lines 8-9 (“a **beveled edge of defined radius** is preferably machined into three faces of the implant . . .”).

Claim 118, which is directed to the assembled bone implant of claim 111, wherein said first cortical bone portion and said second cortical bone portion are in a “stacked position” relative to one another, is supported throughout the specification, including at page 16, lines 13-15 (“In Figure 7, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as to allow **stacking** thereof . . .”); emphasis added in bold.

Claim 119, which is directed to the assembled bone implant of claim 116, wherein said first cortical bone portion and said second cortical bone portion are in a side-by-side position, is supported throughout the specification, including at page 17, lines 11-16 (“In

figure 8A, there is shown an implant 800 composed of two **side-by-side** halves, 801A and 801B. The two halves are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition, or **holes may be formed in each half**, and the halves maintained in contact by forcing **pins through the holes**, in a fashion described above for maintaining stacked implants"); emphasis added in bold.

Claim 120, which is directed to the assembled bone implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone, is supported throughout the specification, including at page 2, lines 20-21 ("the implant is derived from allograft or autograft cortical bone sources"); emphasis added in bold.

Claim 121, which is directed to the assembled bone implant of claim 112, sized and shaped in the form of a "cervical implant," is supported throughout the specification, including at page 2, lines 23-25 ("The **implant** is inserted into the space between adjacent **cervical** vertebrae to provide support and induce fusion of the adjacent vertebrae"); emphasis added in bold.)

Claim 122, which is directed to the assembled bone implant of claim 112, having a height between 7 and 14 mm, is supported throughout the specification, including at page 5, line 2 ("final implant heights from about 7 to about 14 mm may be produced").

Claim 123, which is directed to the assembled bone implant of claim 111, wherein said one or more retention pins comprise a "cancellous bone" portion, is supported throughout the specification, including at Fig. 9, the description of Fig. 9 at page 3, lines 13-15 ("bringing more than one implant into contact with each other and having a **cancellous** plug . . . located in the central canal of each stacked implant, thereby **acting as a retention pin**") and at page 17, lines 4-9 ("By press-fitting the two implants together using an appropriately shaped **cancellous** plug 905 . . . optionally treated with bone morphogenetic protein and the like, the two implants 901 and 902 are retained in registered juxtaposition to form the implant 900.")

Claim 124, which is directed to the assembled bone implant of claim 123, wherein the "cancellous bone portion is treated with a bone morphogenetic protein" (BMP), is supported throughout the specification, including at page 17, lines 4-9 ("By press-fitting

the two implants together using an appropriately shaped cancellous plug **905** . . . optionally treated with **bone morphogenetic protein** and the like, the two implants **901** and **902** are retained in registered juxtaposition to form the implant **900**"); emphasis added in bold.

Claim 125, which is directed to the assembled bone implant of claim 112, wherein said implant has two opposing surfaces that are "inscribed with teeth", is supported throughout the specification, including at Fig. 7B; the description of Fig. 7B at page 16, lines 28-31, ("In figure 7B, there is shown the juxtaposition of two implants 700A and 700B, with the drilled holes 701-704 in register to receive pins for maintaining the implants in register. In this view, the adjacent surfaces 710A and 710B have not been **inscribed with teeth**, while the [opposing] **surfaces 711A and 711B have been so inscribed.**"); at page 18, line 6 ("the side faces are machined to display a rough, ridged or grooved surface"); at page 18, lines 10-13 ("an angle 820 for each **tooth** of between 30 and 40 degrees . . . a distance between **tooth** crests of 821 of about 1-2 mm . . . a **tooth** height 823 of between about 0.1 to about 1 mm . . ."); and at page 9, lines 1-3 ("Alternatively, the implant is passed several times over a rigid surface which cuts the desired **tooth profile** into the **upper, lower or both surfaces** of the implant. Preferably, the thus formed teeth angle toward the anterior (convexly curved) face of the implant to prevent backing out of the implant once it is inserted into an appropriately shaped cavity . . ."); emphasis added in bold. xxx

Claim 126, which is directed to a D-shaped implant, is supported by the same disclosures that support claim 111 (assembled implant) and claim 112 (D-shaped). Claim 127, which is directed to the implant of claim 126, wherein said "retention pin is a cortical bone pin," is supported throughout the specification, including at page 5, line 15 ("appropriate **retention pins** made from any desirable material, including **cortical bone.** . . ."); and at page 16, line 23 ("**Pins**, composed of **cortical bone.** . . ."); emphasis added in bold.

Claim 128, which is directed to the assembled implant of claim 126, wherein said retention pin is a "cancellous bone portion is treated with a bone morphogenetic protein," is supported throughout the specification, including at Fig. 9, the description of Fig. 9 at page 3, lines 13-15 ("bringing more than one implant into contact with each other and having a **cancellous** plug . . . located in the central canal of each stacked implant, thereby

acting as a retention pin”) and at page 17, lines 4-9 (“By press-fitting the two implants together using an appropriately shaped **cancellous** plug 905 . . . optionally treated with bone morphogenetic protein and the like, the two implants 901 and 902 are retained in registered juxtaposition to form the implant 900.”); and at page 17, lines 4-9 (“By press-fitting the two implants together using an appropriately shaped cancellous plug **905** . . . optionally treated with **bone morphogenetic protein** and the like, the two implants **901** and **902** are retained in registered juxtaposition to form the implant **900**”); emphasis added in bold.

For all these reasons, the new claims are fully supported by the disclosures in the specification and do not add new matter. The claims are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By:



Donald J. Pochopien, Ph.D.
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
Suite 3400
Chicago, Illinois 60661
(312) 775-8133

Dated: February 16, 2004

J:\open\DJR\Regeneration Technologies\13971US04\13971US04 2nd PAmtd and Resp to NonCompl.doc